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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,708	05/22/2006	Achim Quaiser	009848-0314964	7651

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PILLSBURY WINTHROP SHAW PITTMAN LLP
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER

STEELE, AMBER D

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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08/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,708

Applicant(s)

QUAISER ET AL

Examiner

AMBER D. STEELE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40, 42-47, and 53-76 is/are pending in the application.
- 4a) Of the above claim(s) 60-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40, 42-46 and 53-59 is/are rejected.
- 7) ☒ Claim(s) 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 22, 2009 has been entered.

Status of the Claims

2. The preliminary amendment received on February 18, 2005 canceled claims 1-39 and added new claims 40-76.

The amendment to the claims received on August 6, 2008 amended claims 40, 43, 46, and 53 and canceled claims 41 and 48-52.

The amendment to the claims received on June 22, 2009 amended claims 40, 44, and 53.

Claims 40, 42-47, and 53-76 are currently pending.

Claims 40, 42-47, and 53-59 are currently under consideration.

Election/Restrictions

3. Applicants elected, with traverse, Group I (previous claims 40-59) in the reply filed on March 12, 2008. Claims 60-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Priority

4. The present application claims status as a 371 (national stage) of PCT/EP03/09223 filed August 20, 2003. In addition, the present application claims foreign priority to EP 02018210.1 filed August 20, 2002.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Invention as Claimed

6. A device for the isolation and/or purification of nucleic acid molecules comprising at least two layers: a first layer being adapted to bind or inactivate inhibitors of the activity of reagents or enzymes used in nucleic acid manipulation wherein said first layer comprises polyvinylpyrrolidone (PVP) or polyvinylpolypyrrolidone (PVPP) and a second layer being adapted to separate a plurality of nucleic acid molecules with respect to their size and wherein said first layer is a first phase of a gel and said second layer is a second phase of said gel and wherein said first layer is arranged above the second layer and wherein said second layer is substantially free of PVP when said first layer comprises PVP and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP and variations thereof.

7. Please note: the specification, page 35, last paragraph states that approximately 1/4, 1/3, or up to 80-95% of the gel can be one layer. In addition, "above" is defined as vertical or horizontal (see page 8).

Please refer to MPEP § 2114 regarding apparatus claims and MPEP § 2115 regarding materials worked upon by the apparatus wherein claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function (*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)). Recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus and expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim (*Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969)). Inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims (*In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) and as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

New Objection

8. Claim 47 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Withdrawn Rejections

9. The rejection of claim 43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement regarding new matter was withdrawn in the Advisory Action mailed on January 28, 2009.

10. The rejections of claim 53 under 35 U.S.C. 112, second paragraph regarding the trademarks/trade names Sepharose™, Sephadex™, Sephacryl™, BioGel™, and Superose™ and

regarding the composition of the first and second layers are withdrawn in view of the claim amendments received on June 22, 2009.

11. The rejection of claims 40, 42-47, and 53-59 under 35 U.S.C. 102(b) as anticipated by Young et al. Applied and Environmental Microbiology 59(6): 1972-1974, 1993 (provided by applicants in the IDS) is withdrawn in view of the claim amendments received on June 22, 2009.

Maintained Rejection

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 40, 42-46, and 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffman WO 99/00168 published January 7, 1999 (provided by applicants in the IDS) and Berthelet et al., 1996, Rapid, direct extraction of DNA from soils for PCR analysis using polyvinylpyrrolidone spin columns, FEMS Microbiology Letters, 138: 17-22 (provided by applicants in the IDS).

For present claims 40, 42-46, and 53-59, Coffman teaches a two phase column comprising a top layer of adsorptive media and a second layer of size exclusion media wherein various adsorptive media can be utilized including commercially available reagents comprising agarose and the first adsorptive layer is utilized to extract various components of the sample including proteins (i.e. second layer substantially free of proteins, etc.) wherein proteins can be separated

from DNA and/or RNA (please refer to the entire specification particularly the abstract; pages 2-10; Figures 1-2). Please refer to MPEP § 2114 and 2115.

However, Coffman does not teach a first layer comprising PVP or PVPP.

For present claims 40, 42-46, and 53-59, Berthelet et al. teach utilizing PVPP columns to extract DNA from soil samples (please refer to the entire reference particularly the abstract; Materials and Methods section).

The claims would have been obvious because the substitution of one known element (i.e. various column materials taught by Coffman) for another (i.e. PVPP column material taught by Berthelet et al.) would have yielded predictable results (i.e. extraction of DNA) to one of ordinary skill in the art at the time of the invention. In addition, the claims would have been obvious because a particular known technique (i.e. two phase chromatography taught by Coffman and PVPP column extraction of DNA taught by Berthelet) was recognized as part of the ordinary capabilities of one skilled in the art. Furthermore, Berthelet et al. teach that the PVPP columns provided rapid separation and enhanced the removal of inhibitory humic acid contaminants from soil extracts resulting in purer preparations of DNA more suitable for PCR (see page 20, section 3). See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Arguments and Response

14. Applicants' arguments directed to the rejection under 35 USC 103 (a) as being unpatentable over Coffman and Berthelet et al. for claims 40, 42-46, and 53-59 were considered but are not persuasive for the following reasons.

Applicants contend that neither Coffman nor Berthelet et al. teach a device comprising two distinct layers wherein the first layer comprises PVP or PVPP and the second layer is substantially free of PVP or PVPP.

Applicants' arguments are not convincing since the teachings of Coffman and Berthelet et al. render the device of the instant claims *prima facie* obvious. Coffman teach a device comprising an adsorptive media on top of a size exclusion media (i.e. first and second layers) wherein neither layers comprises PVP or PVPP and teaches that the adsorptive media can comprise reverse phase media, ion exchange media, normal phase media, hydroxyapatite media, metal chelating media, affinity media, any other media which binds molecules in one buffer and releases molecules in a different buffer, hydrophobic interaction media which may selectively retain or repel the desired product but repel or retain the buffer including media and the device is utilized to remove impurities, to perform one step adsorptive and size exclusion processes, and to isolate or purify nucleic acids (please refer to the entire reference particularly the abstract; Figures 1-2; pages 2, 4, 6, 7, 9). Berthelet et al. teach PVPP spin columns to extract DNA from soil (see the entire reference particularly the abstract; section 2.1).

The claims would have been obvious because the substitution of one known element (i.e. various column materials taught by Coffman) for another (i.e. PVPP column material taught by Berthelet et al.) would have yielded predictable results (i.e. extraction of DNA) to one of ordinary skill in the art at the time of the invention. In addition, the claims would have been obvious because a particular known technique (i.e. two phase chromatography taught by Coffman and PVPP column extraction of DNA taught by Berthelet) was recognized as part of the ordinary capabilities of one skilled in the art. Furthermore, Berthelet et al. teach that the

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PVPP columns provided rapid separation and enhanced the removal of inhibitory humic acid contaminants from soil extracts resulting in purer preparations of DNA more suitable for PCR (see page 20, section 3). See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,770,698, Song et al. Electrophoresis 22: 3688-3698, 2001, and Wang et al. Electrophoresis 23: 1460-1466, 2002.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639

August 18, 2009